

REMARKS

Claims 1-10 are pending in the present application. Claims 1-10 are rejected. Claims 1, 4 and 6-8 are herein amended. No new matter has been entered.

Claim Rejections - 35 U.S.C. §112

Claims 1-10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The Examiner asserts that in claim 1, the significance of the language “as the essential component” is unclear. Applicants herein delete the phrase, “as the essential component”.

Within claims 4, 6 and 7, the Examiner asserts that the phrases “the content of isocyanate ...”, “the viscosity ...”, “the content of alkaline ...”, “the film ...”, and “the wet 100% modulus ...” lacks antecedent basis. Applicants herein effect amendments to claims 4, 6 and 7 to address the above rejections.

The Examiner asserts that because statements of intended use do not carry patentable weight, the subject matter of claims 8 and 9 fail to further limit the subject matter of claim 1. Applicants therefore effect minor amendment to claim 8 to recite that the medical adhesive is medically suitable for bonding body tissues.

Double Patenting

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7, 8, 10-16 and 18-20 of copending

Application No. 10/499,331 in view of USP 5,527,266 to Hiraishi et al., or US 2003/0335239 to Nakamura et al., or US 2004/0033251 to Sparer et al., or US 2005/0060022 to Felt et al.

Since the present invention is not rendered obvious over the cited references, as noted hereinbelow, Applicants submit that the double-patenting rejection is overcome, and should be withdrawn.

Claim Rejections - 35 U.S.C. §103(a)

Claims 1-10 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 03/051952 in view of Hiraishi et al. or Nakamura et al. or Sparer et al. or Felt et al. The Examiner cites pages 9, 28, 40 and 47 of GB 2,399,345 (English equivalent of WO 03/051952).

The Examiner asserts that WO 03/051952 discloses medical adhesives having the same properties and derived from nearly the same reactants as those instantly claimed, but fails to disclose the presently claimed phenolic radical scavenger. However, the Examiner asserts that the use of phenolic antioxidants that correspond to Applicants' claimed phenolic radical scavenger within polyurethanes, suitable for use within medical applications, was known at the time of invention.

The Examiner concludes that it would have been obvious to incorporate known phenolic antioxidants within the urethane based composition of the primary reference, so as to obtain an improved and further stabilized adhesive composition.

The Examiner is essentially asserting that the present invention with the exception of the phenolic radical scavenger (PRS) is known and taught by WO 03/051952. The Examiner is asserting that one skilled in the art would have been motivated to add a PRS to the invention of WO 03/051952 in order to stabilize the invention thereof, because PRS are known for the same uses as in the present invention.

In order to overcome the rejection, Applicants submit that the particularly claimed combination of hydrophilic urethane prepolymer and a phenolic radical scavenger provides a result that is unexpected over what might have been expected based on the prior art teachings about hydrophilic urethane prepolymers and phenolic radical scavengers.

According to the present invention, the medical adhesive comprises a hydrophilic urethane prepolymer (UP) and a phenolic radical scavenger (PRS).

Applicants note that when PRS is contained in the adhesive and the urethane prepolymer is obtained from a fluorine-containing nonaromatic polyisocyanate, the cured adhesive does not change over time. Further, wet adhesive strength is high from the beginning of adhesion and hardly changes over time, as noted in the Examples of the present application. As will be discussed later, the phenolic radical scavenger provides an effect that would not have been expected from the cited references and the common technical knowledge at the time of filing of the present application.

If PRS is not used in the adhesive comprising a urethane prepolymer obtained from a fluorine-containing nonaromatic polyisocyanate, the cured adhesive changes over time and

changes into viscous liquid. Adhesive strength is high at the beginning of adhesion, but is lost as viscous liquid forms, as demonstrated in the Comparative Examples of the present application.

Applicants further note that if the urethane prepolymer is not obtained from a fluorine-containing nonaromatic polyisocyanate, the cured adhesive and the adhesive strength hardly change over time regardless of phenolic radical scavenger. The adhesive strength is lower than that of the present invention. Therefore, in such case there is no effect of the presence of the PRS.

The unexpected effect of the particularly claimed components of the present invention discussed above is shown and discussed by the comparative experiments, which are detailed in the attached declaration under 37 C.F.R. §1.132.

Applicants characterize the cited documents as follows:

WO03/051952 (and US10/499,331) discloses a polymer comprising an isocyanato group-containing polymer derived from a polyisocyanate (A) and an active hydrogen-containing polymer (B). WO03/051952 teaches the use of fluorine-containing aliphatic polyisocyanates as polyisocyanate (A). However, WO03/051952 is silent about a phenolic radical scavenger. Applicants note that the polymer of WO03/051952 is analogous to Comparative Examples of the present application.

Hiraishi et al. discloses a polyurethane prepolymer obtained from a polyol compound and a polyisocyanate compound. Hiraishi et al. uses IRGANOX 1010 as an antioxidant in its Example. Examples of the polyisocyanate compounds include aromatic and aliphatic polyisocyanate compounds (column 3, lines 21 to 37). However, Applicants note that Hiraishi et al.

does not teach the use of fluorine-containing nonaromatic polyisocyanates as the polyisocyanate compound.

Nakamura et al. discloses an adhesive comprising a urethane urea resin made from a polyol (a), a polyisocyanate (b), a polyamine (c) and an unsaturated compound (d). Nakamura et al. teaches phenolic type antioxidants in paragraphs [0177] to [0180]. Examples of the polyisocyanate include aromatic and aliphatic compounds ([0065] to [0073]). However, Applicants note that Nakamura et al. does not teach to use fluorine-containing nonaromatic polyisocyanates as the polyisocyanate.

Sparer et al. discloses an active agent delivery system comprising an active agent and a polymer blend comprising a polyurethane and a second polymer. Sparer et al. uses IRGANOX 1010 as an antioxidant Example 1. Sparer et al. teaches that poly(carbonate urethane) 75D used in Examples is obtained from aromatic diisocyanate. However, Applicants note that Sparer et al. is silent about fluorine-containing nonaromatic polyisocyanates.

Felt et al. discloses a stent device comprising a tubular polyurethane body. Felt et al. uses IRGANOX 1010 as an antioxidant (Table I) in the preparation of polyurethane. Examples of the polyisocyanate, which is used to prepare polyurethane, include aromatic and aliphatic compounds ([0026]). However, Felt et al. is silent about fluorine-containing nonaromatic polyisocyanates.

Hiraishi et al., Nakamura et al., Sparer et al. and Felt et al. use antioxidants. Generally, antioxidants are used in the preparation of polyurethane to prevent yellowing of urethane resin (yellowing at the time of production or over time) or prevent cracks in coating comprising

urethane polymer. These references use the antioxidants for a general purpose. The effect of the PRS of the present invention, that is, continuation of adhesion strength (prevention of decrease of adhesion strength), is completely different from generally known effect of antioxidants, and would not have been expected from the references.

Furthermore, the cited references do not teach or suggest the effect of a combination of the PRS and the urethane prepolymer obtained from the fluorine-containing nonaromatic polyisocyanate. The cited references teach either to use the fluorine-containing nonaromatic polyisocyanate but not the PRS, or to use the PRS but not the fluorine-containing nonaromatic polyisocyanate.

Still furthermore, a person skilled in the art would not have had prompting or motivation to combine PRS with a urethane prepolymer obtained from a fluorine-containing nonaromatic polyisocyanate since additional PRS provides no effect on adhesive strength as shown by the comparative experiments, as described by Comparative Examples 6 to 11.

Accordingly, the present invention would not have been easily attained from the cited references and the effect thereof would not have been expected. The present invention is not rendered obvious by the cited references, alone or in combination.

In view of the aforementioned amendments and accompanying remarks, Applicants submit that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date.

Application No. 10/594,627
Attorney Docket No. 063012

Amendment under 37 C.F.R. §1.111
Amendment filed December 26, 2007

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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Enclosure: Declaration under 37 C.F.R. §1.132